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European Medicines Agency

CTIS newsflash 11 February 2022

Introduction

Welcome to the second CTIS newsflash. This newsflash provides updates on key facts and figures regarding CTIS usage, as well as links to useful reference materials.

Key metrics

Metrics reported cover the period 31/01/2022-9/02/2022.

Total number of logins to CTIS: 2,053

- This metric represents the total sum of unique logins by individual users per day during the period

- **Number of draft applications in CTIS on 9/02/2022:** 87

  - This metric counts the number of applications with status "Draft" in CTIS

- **Number of submitted applications in CTIS:** 3

News spotlight

The first multinational clinical trial has been submitted in CTIS. This trial is also the first trial which has transitioned from the regime of the Clinical Trials Directive to the Clinical Trials Regulation via submission to CTIS.

Did you know?

A core aspect of the Clinical Trials Regulation is increasing the efficiency and ease of submission of multinational clinical trial applications. With CTIS, sponsors can submit a single clinical trial application covering up to 30 EU/EEA countries, all in one unified electronic process. CTIS also allows sponsors to easily expand authorised trials to additional Member States using an 'Additional Member State

concerned' application, which can facilitate patient recruitment while ensuring no unnecessary duplication of documentation.

Helpful hint

If you encounter any questions or issues when using CTIS, it is recommended to first consult the CTIS training and support materials to see if your question has been answered in existing documents. If you cannot find the answer to your question in the training and support materials, the EMA Service Desk is here to help. Please raise a ticket via the Service Desk and a colleague will work with you to find a solution.

CTIS bitesize talks

The first CTIS bitesize talk will take place on 24 February 2022 at 14:00-15:30. The CTIS bitesize talks allow sponsors to learn about a dedicated CTIS functionality, while also providing time to ask practical questions. The first talk covers the user access and role management functionality in CTIS. The talk will be live broadcasted from the EMA event page and no registration is needed. More information is available here.

Eudravigilance short training course for sponsors: reminder

EMA offers a short training courses on EudraVigilance for clinical trial sponsors with the organisational support of DIA. The courses explain how to report suspected unexpected serious adverse reactions (SUSARs) to EudraVigilance via EVWEB. Courses are available 9-11 March and 4-6 May 2022. More information can be found on the EudraVigilance training and support webpage.

More information

Users can review Module 10 – Create, submit and withdraw a clinical trial for more information on initial clinical trial applications and additional Member State concerned applications. In addition, a video recording of a CTIS demonstration held for stakeholders involved in the CTIS project has been published on the EMA website. The demonstration provides an in-depth look into all CTIS functionalities, including how to submit a clinical trial application.

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